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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/622,727 | 07/21/2003 | Jacques Bartholeyns | 0508-1011-1 | 2789 |

466 7590 10/31/2006

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| EXAMINER | |
|---|---|
| YU, MISOOK | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/622,727 | BARTHOLEYNS ET AL. | |
| | Examiner | Art Unit | |
| | MISOOK YU, Ph.D. | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *07 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *7-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/21/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

Applicant's election with traverse of group 1, claims 1-6 in the reply filed on 08/07/2006 is acknowledged. The traversal is on the ground(s) that group I and II are sufficiently related, and the particular administration schedule and dose of group II are species of group I. This is not found persuasive because the different inventions have different designs because group I does not require the specific doses and regime schedule of the various art-known chemotherapeutic agents, as required by group II invention. Since the instant specification is not about discovery of a chemotherapeutic agent being used in the claimed invention, the specific doses and schedules are considered critical, and searching of group II put a serious burden on the examiner, especially the non-patent literature search involves a serious burden. The claimed invention is treatment of cancer or infectious disease. The requirement is still deemed proper and is therefore made FINAL.

Claims 7-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-21 are pending and claims 1-6 are examined on merits.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 is confusing as to how the mononuclear derived cells in claim 5 is related to the mononuclear derived cells in the base claim 1. It is not clear whether two populations (i.e. moncytes derived cells of base claims and moncytes derived cells cultured for 5 to 10 days) of monocytes being used in claim 5, or claim 5 futher limits the monocyte derived cells of the base claim to be the cells cultured for 5 to 10 days.

For the purpose of this Office action, the Office will assume that the cells being used in claim 5 further limits the cells of the base claim to be cells cultured for 5-10 days. However, this treatment does not relieve applicant the burden of responding to this rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, and 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartoleyns et al (IDS, Immunobiology, 1996, vol. 195, pages 550-562).

Claims 1, 2, and 4-6 are drawn to method of treating cancer using monocyte derived cells and chemotherapy, wherein the monocyte derived cells and chemotherapy administered simultaneously (claim 2), in injection form (claim 4), the monocyte derived cells are cultured for 5-10 days (claims 5 and 6).

Bartoleyns et al., teach method of treating cancer using monocyte derived cells (i.e. activated macrophages, note Table 1 at page 553), and also teach how to make mononuclear derived cells at page 551 and Figure 1. Bartoleyns et al., at page 557, 1st full paragraph teach "Stimumation of the immune response against established tumor might only be successful when the tumor burden has been reduced to manageable proportions by prior surgery, chemo- or radiotherapy.

Therefore, one of ordinary skill would be motivated to use monocyte derived cells (i.e. activated macrophages) in combination with other art-known chemotherapy with a reasonable expectation of success for cancer therapy since the efficacy of monocyte derived cells is taught in Bartoleyns et al.,, and Bartoleyns et al., suggest chemotherapy to reduce the tumor burden for stimulation of immune response by monocyte derived cells.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bartoleyns et al (IDS, Immunobiology, 1996, vol. 195, pages 550-562) as applied to

claim 1 above, and further in view of Gehl et al (Seminars in Oncology, vol. 23, No. 6, Supp 15, December 1966, pages 35-38).

Claim 3 is drawn to method of cancer treatment using monocyte derived cell and various art-known chemotherapeutic agents, and taxol being one of them.

See above what Bartoleyns et al., teach. Bartoleyns et al., do not mention various chemotherapeutic agents listed in claim 3. However, Gehl et al teach taxol is well known chemotherapeutic agent used in cancer treatment art.

Therefore, one of ordinary skill would be motivated to use monocyte derived cells (i.e. activated macrophages) in combination with taxol with a reasonable expectation of success for cancer therapy since the efficacy of monocyte derived cells is taught in Bartoleyns et al.,, and Bartoleyns et al., suggest chemotherapy to reduce the tumor burden for stimulation of immune response by monocyte derived cells, and Gehl et al teach that taxol is well known chemotherapeutic agent.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MISOOK YU, Ph.D.
Primary Examiner
Art Unit 1642